

ASSEMBLY BILL

No. 1823

Introduced by Assembly Member Bonilla

February 8, 2016

An act to add Part 7 (commencing with Section 101990) to Division 101 of the Health and Safety Code, relating to clinical trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 1823, as introduced, Bonilla. California Cancer Clinical Trials Program.

Existing law, the Inclusion of Women and Minorities in Clinical Research Act, requires a grantee, defined to include, but not be limited to, a college or university that conducts clinical research using state funds, to ensure that women and minority groups are included as subjects in each research project, except as provided. Existing law establishes the University of California.

This bill would provide for the establishment of the California Cancer Clinical Trials Program and request that the University of California designate a nonprofit organization as the program administrator governed by a board of at least 5 members appointed by the president of the university. The bill would authorize the program administrator to solicit and receive funds from various specified sources for purposes of the program and would authorize the board, upon receipt of at least \$500,000 in funding, to establish program to increase patient access to eligible cancer clinical trials in underserved or disadvantaged communities and populations, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) According to Public Policy Institute of California's Future: Health Care report released in 2015, significant health disparities exist among socioeconomic, racial, ethnic, and regional groups in California. African Americans and persons with a high school education or less have significantly lower life expectancies than other groups of people, and individuals in some regions of the state or in particular communities face other significant health obstacles.

(b) The ability to translate medical findings from research to practice relies largely on having robust patient participation and a diverse participation pool. A low participation rate or a homogenous participant group prevents segments of the population from benefiting from advances achieved through clinical research and creates uncertainties over the applicability of research findings. Diverse patient participation in a clinical trial depends, in part, on whether a participant can afford ancillary costs like transportation, childcare, or lodging during the course of his or her participation. A national study in 2015 found that patient households making less than \$50,000 annually were almost 30 percent less likely to participate in clinical trials. This disparity threatens one of the most basic ethical underpinnings of clinical research, the requirement that the benefits of research be made available equitably among all eligible individuals.

(c) California is home to the following 10 National Cancer Institute-Designated Cancer Centers that perform cancer clinical trials research:

(1) University of California, Irvine Chao Family Comprehensive Cancer Center.

(2) City of Hope Comprehensive Cancer Center.

(3) University of California, Los Angeles, Jonsson Comprehensive Cancer Center.

(4) Salk Institute Cancer Center.

(5) Sanford Burnham Prebys Medical Discovery Institute.

(6) Stanford Cancer Center.

(7) University of California, Davis, Comprehensive Cancer Center.

(8) University of California, San Diego, Moores Cancer Center.

1 (9) University of California, San Francisco, Helen Diller Family
2 Comprehensive Cancer Center.

3 (10) University of Southern California, Norris Comprehensive
4 Cancer Center.

5 (d) Cancer is the cause of almost one in four deaths in California.
6 It is the second leading cause of death for Californians and the
7 primary cause of death among Californian Asian/Pacific Islanders.
8 A Californian will be diagnosed with cancer approximately every
9 four minutes, and every ten minutes a Californian will die of
10 cancer. African American Californians in particular face
11 disproportionally higher rates of cancer incidence and mortality
12 compared to other races and ethnicities.

13 (e) Addressing barriers faced by medically underserved and
14 underrepresented individuals in cancer and other clinical trials and
15 improving access to survivorship resources and services through
16 partnerships with hospitals, regional and community cancer centers,
17 and nonprofit organizations are some of the strategies
18 recommended by the California Dialogue on Cancer, established
19 in 2002 by California's Comprehensive Cancer Control Program
20 to reduce the burden of cancer in California.

21 (f) According to the National Cancer Institute Cancer Clinical
22 Trials Resource Guide, some of the barriers preventing individuals
23 with cancer or at high risk of developing cancer from participating
24 in clinical trials are direct and indirect financial and personal costs,
25 including travel and child care expenses.

26 (g) It is the intent of the Legislature to enact legislation that
27 would establish a program to enable willing patients of low to
28 moderate income to participate in cancer and other clinical trials
29 in order to boost participation rates, ensure these trials are widely
30 accessible, improve the development of therapies, and enhance
31 innovation.

32 SEC. 2. Part 7 (commencing with Section 101990) is added to
33 Division 101 of the Health and Safety Code, to read:

34
35 PART 7. CALIFORNIA CANCER CLINICAL TRIALS
36 PROGRAM
37

38 101990. For purposes of this part, the following definitions
39 apply:

1 (a) “Board” means the Board of Trustees of the California
2 Cancer Clinical Trials Program.

3 (b) “Fund” or “clinical trials fund” refers to a fund established
4 by the Program Administrator to support the program.

5 (c) “Program” means the California Cancer Clinical Trials
6 Program.

7 (d) “Program administrator” means the nonprofit organization
8 designated by the University of California pursuant to paragraph
9 (1) of subdivision (a) of Section 101991.

10 (e) “University” means the University of California.

11 (f) “Eligible cancer clinical trial” means a clinical trial conducted
12 in the state that targets cancer and is regulated by the federal Food
13 and Drug Administration.

14 101991. (a) The university is hereby requested to do all of the
15 following:

16 (1) Establish and designate, or designate, a nonprofit
17 organization, governed by the Nonprofit Public Benefit Corporation
18 Law (Part 1 (commencing with Section 5110) of Division 2 of
19 Title 1 of the Corporations Code) to administer the program.

20 (2) Establish a governing board of the program administrator
21 consisting of at least five members, appointed by the president of
22 the university to represent institutions and individuals performing,
23 participating in, and supporting eligible cancer clinical trials in
24 California.

25 (b) All persons appointed to the board shall have an interest in
26 increasing and diversifying access to eligible cancer clinical trials
27 and the ability and desire to solicit funds for the purpose of
28 increasing and diversifying access to clinical trials as provided in
29 this part.

30 (c) Members of the board shall serve without compensation. A
31 board member shall be reimbursed for any actual, necessary, and
32 reasonable expenses incurred in connection with his or her duties
33 as a board member.

34 101992. (a) The university may participate in the program as
35 the program administrator, a beneficiary, or both.

36 (b) Prior to establishing the board, the university may pursue
37 any federal, state, or internal approvals, authorizations, or advice
38 it deems necessary to the university’s participation in the program.

39 (c) The university may decline to establish or participate in the
40 program.

1 101993. The program administrator may solicit and receive
2 funds from business, industry, foundations, research organizations,
3 government agencies, individuals, and other private and public
4 sources for the purpose of administering the program to increase
5 patient access to clinical trials targeting cancer.

6 101993.5. Any money allocated by the university to establish
7 and operate the program shall be reimbursed to the university,
8 from moneys donated to the fund.

9 101994. (a) Upon receipt of at least five hundred thousand
10 dollars (\$500,000) in funding for the program by the program
11 administrator, the board shall establish the Cancer Clinical Trials
12 Grant Program to increase patient access to eligible cancer clinical
13 trials in underserved or disadvantaged communities and
14 populations, including among women and patients from racial and
15 ethnic minority communities and socioeconomically disadvantaged
16 communities. The board shall determine the criteria to award grants
17 to support cancer clinical trials. The board may award grants to
18 any or all of the following:

19 (1) Public and private research institutions and hospitals that
20 conduct eligible cancer clinical trials.

21 (2) Nonprofit organizations described in Section 501(c) of the
22 Internal Revenue Code and do either of the following:

23 (A) Specialize in direct patient support for improved clinical
24 trial enrollment and retention.

25 (B) Engage in research on health disparities.

26 (b) Grants awarded pursuant to subdivision (a) shall be used for
27 activities to increase patient access to eligible cancer clinical trials,
28 including, but not limited to, any of the following:

29 (1) Patient navigator services or programs.

30 (2) Education and community outreach.

31 (3) Patient-friendly technical tools to assist patients in
32 identifying available clinical trials.

33 (4) Translation and interpretation services of clinical trial
34 information.

35 (5) Counseling services for clinical trial participants.

36 (6) Well-being services for clinical trial participants, including,
37 but not limited to, physical therapy, pain management, stress
38 management, and nutrition management.

(7) Payment of ancillary costs for patients and caregivers, including, but not limited to all of the following during and related to participation in the clinical trial:

(A) Airfare.

(B) Lodging.

(C) Rental automobile and fuel for the automobile.

(D) Local public transportation by bus, train, or other public transportation.

(E) Meals.

(F) Dependent child care.

(8) Research on the effectiveness of these and other measures to increase patient access to clinical trials.

101995. (a) The board shall require grantees to submit any reports it deems necessary to ensure the appropriate use of funds consistent with the purposes of this part and the terms of any grant awards.

(b) The university may require the board to submit reports pertaining to the board's activities to the Regents of the University of California, including, but not limited to, the following information:

(1) An accounting of funds collected and expended.

(2) An evaluation of the program.

(c) Recommendations regarding the program.

101996. (a) (1) If the university determines at any time that the moneys in the fund are insufficient to establish or sustain the program, the university may terminate the program.

(2) All moneys in the fund remaining after expenses are paid shall, prior to dissolution, be allocated to one or more organizations described in subdivision (a) of Section 101994.

(b) If the foundation does not receive five hundred thousand dollars (\$500,000) or more by January 1, 2021, moneys remaining after the repayment required pursuant to subdivision (a) of Section 101993.5 shall be returned to the donors on a pro rata basis.